

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12364	Date: November 16, 2023
	Change Request 13429

SUBJECT: NCD 220.6.20 - Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to announce that effective October 13,2023, CMS removed NCD 220.6.20 from Publication 100-03, the NCD Manual, ending coverage with evidence development (CED) for positron emission tomography (PET) beta amyloid imaging and permitting Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act.

EFFECTIVE DATE: October 13, 2023

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: December 19-2023 - A/B MACs; April 1, 2024 - CWF, MCS, FISS

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/220.6/20/Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (RETIRED)

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

Pub. 100-03	Transmittal: 12364	Date: November 16, 2023	Change Request: 13429
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SUBJECT: NCD 220.6.20 - Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease

EFFECTIVE DATE: October 13, 2023

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: December 19, 2023 - A/B MACs; April 1, 2024 - CWF, MCS, FISS

I. GENERAL INFORMATION

A. Background: Effective for claims with dates of service on or after, September 27, 2013, CMS covered the use of Positron Emission Tomography (PET) beta amyloid imaging to improve health outcomes for Medicare beneficiaries with dementia or neurodegenerative disease in certain scenarios under National Coverage Determination (NCD) 220.6.20. Since then, Medicare allowed coverage for one PET beta amyloid imaging scan per lifetime through coverage with evidence development (CED) to: (1) develop better treatments or prevention strategies for Alzheimer’s Disease (AD), or, as a strategy to identify subpopulations at risk for developing AD, or (2) resolve clinically difficult differential diagnoses (e.g., frontotemporal dementia (FTD) versus AD) where the use of PET beta amyloid imaging appears to improve health outcomes, when the patient is enrolled in an approved clinical study under CED. CMS reconsidered NCD 220.6.20 and made a final determination on October 13, 2023, to remove the NCD in its entirety.

B. Policy: Effective for claims with dates of service on and after October 13, 2023, CMS removed NCD 220.6.20 from Publication 100-03, the NCD Manual, ending CED and the once-in-a-lifetime requirement for PET beta amyloid imaging and permitting Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act. See NCD Manual chapter 1, section 220.6.20, Claims Processing Manual, chapter 13, section 60.12, and the attached spreadsheet.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13429 - 03.1	Effective for claims with dates of service on and after October 13, 2023, as a result of the reconsideration of NCD 220.6.20 Beta Amyloid PET in Dementia/Neurodegenerative Disease, contractors shall be aware that this NCD has been removed.	X	X							
13429 - 03.2	Effective for claims with dates of service on and after October 13, 2023, contractors shall determine coverage for NCD	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	220.6.20.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			DME MAC	CEDI	
		A	B	HHH			
13429 - 03.3	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get MLN content notifications. You don’t need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X				

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is

not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

NCD:	220.6.20
NCD Title:	Beta Amyloid PET for Dementia and Neurodegenerative Disease
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1753OTN.pdf
MCD:	http://www.cms.gov/medicare-coverage-database/details/ncd-
	CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
ICD-10 CM	ICD-10 DX Description

NCD:	220.6.20
NCD Title:	Beta Amyloid PET for Dementia and Neurodegenerative Disease
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1753OTN.pdf
MCD:	http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=288&ncdver=3&bc=AgAAgAAAAAAAAA%3d%3d&

	ICD-10 PCS	ICD-10 PCS Description
	N/A	N/A

NCD:	220.6.20
NCD Title:	Beta Amyloid PET for Dementia and Neurodegenerative Disease (CR8526, CR9751 CR10184, CR12842, CR13249)
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1753QTN.pdf
MCD:	http://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=265&NcaName=Beta+Amyloid+Positron+Emission+Tomography+in+Dementia+and+Neurodegenerative+Disease&bc=AiAAAAACA AAAA%3d%3d&

Part A	Rule Description Part A	Proposed HCPCS/CPT Part A	Frequency Limitations	TOB (Part A)	Revenue Code Part A	Modifier Part A	Provider Specialty	Proposed MSN Message Part A	Proposed CARC Message Part A	Proposed RARC Message Part A
	<i>Effective 10/13/23, as a result of the reconsideration of NCD 220.6.20, and under section 1862(a)(1)(A) of the Social Security Act, this NCD has been removed. Coverage determinations are now made by the MACs</i>									
Part A	A/MAC, FISS: One of two PET imaging codes shall be required and one HCPCS dx radiopharmaceutical must be billed on claim. All codes relative to a clinical trial dx Z00.6, Q0 modifier, NCT number, condition code 30, value code D4 (new FISS RC will require) must all be on claim along with an additional, approved diagnosis.	78811 or 78814 and A9586 or Q9982 or Q9983	NA	NA	NA	Q0	N/A	15.20 15.4 16.77	16	M20 M44 M49
Part A	CWF, FISS: For claims with DOS on or after 9/27/13, CWF shall deny/reject claims for more than one PET Aβ scan, HCPCS A9586 (effective 1/1/13), Q9982, or Q9983 (effective 7/1/16) in a patient's lifetime. NOTE: This edit shall be overridable.	78811 or 78814 and A9586 or Q9982 or Q9983	1 per patient lifetime	NA	NA	NA	NA	20.12	149	N587
Part A	A/MAC: Shall identify claims with TOB 85X when revenue code is 096X, 097X, or 098X as professional claims.	78811 or 78814 and A9586 or Q9982 or Q9983	NA	85X	096X 097X 098X	NA	NA	NA	NA	NA
Part A	Florbetapir F18 NCD # 0002-1200-01 may be listed on claim for better drug identification.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

NCD: 220.6.20										
NCD Title: Beta Amyloid PET for Dementia and Neurodegenerative Disease (CR8526, CR9751 CR10184, CR12842, CR13249)										
IOM: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1753QTN.pdf										
MCD: http://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=265&NcaName=Beta+Amyloid+Positron+Emission+Tomography+in+Dementia+and+Neurodegenerative+Disease&bc=AiAAAAACAAAA%3d%3d&										
Part B	Rule Description Part B	Proposed HCPCS/CPT Part B	Frequency Limitations	POS (Part B)	n/a	Modifier Part B	Provider Specialty	Proposed MSN Message Part B	Proposed CARC Message Part B	Proposed RARC Message Part B
	<i>Effective 10/13/23, as a result of the reconsideration of NCD 220.6.20, and under section 1862(a)(1)(A) of the Social Security Act, this NCD has been removed. Coverage determinations are now made by the MACs</i>									
Part B	B/MAC, MCS: One of two PET imaging codes is required and one HCPCS dx radiopharmaceutical must be billed on claim. All codes relative to a clinical trial include dx Z00.6, -Q0 modifier, NCT number, along with an additional, approved dx.	78811 or 78814 and A9586 or Q9982 or Q9983	NA	N/A	N/A	Q0	N/A	15.20 15.4 16.77	16	M64 M20
Part B	Florbetapir F18 NCD # 0002-1200-01 may be listed on claim for better drug identification.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Revision Explanation										
Add A9599, add RARC N517, N519, N586, CARC 149, MSN 20.12, TOB 85X , rev codes 096X, 097X, 098X and additional dx requirement - see dx tab.										
Change A/B MACs to A/MACs or B/MACs for clarity.										
<p>CR9751: Effective 1/1/16 add C9458 & C9459 to A/MAC instructions. Effective 6/30/16 end-date C9458 & C9459. New FISS RC to require value code D4. Add new codes Q9982 and Q9983 effective 7/1/16. MCS edit 010K & 011K. Revise CARC/RARC messages per CORE.</p>										
<p>CR10184: End-date A9599 NOC code effective 1/1/18. MCS audit 010K/011K to be updated. FISS to delete logic for non-NCD RCs and replace w/59CXX RCs effective 10/1/15. FISS to end-date non-NCD RC 32718 effective 10/1/15 and create new 59XXX NCD RCs. FISS to delete RC 39906.</p>										
<p>CR12842: End-date: ICD-10 dx F01.51, F02.81, and F03.91 effective 9/30/2022. Note descriptor changes for ICD-10 dx: F01.50, F03.90, G31.09, and G31.84 effective 10/1/2022. Add ICD-10 dx: F01.511, F01.518, F01.52, F01.53, F01.54, F01.A0, F01.A11, F01.A18, F01.A2, F01.A3, F01.A4, F01.B0, F01.B11, F01.B18, F01.B2, F01.B3, F01.B4, F01.C0, F01.C11, F01.C18, F01.C2, F01.C3, F01.C4, F02.811, F02.818, F02.82, F02.83, F02.84, F02.A0, F02.A11, F02.A18, F02.A2, F02.A3, F02.A4, F02.B0, F02.B11, F02.B18, F02.B2, F02.B3, F02.B4, F02.C0, F02.C11, F02.C18, F02.C2, F02.C3, F02.C4, F03.911, F03.918, F03.92, F03.93, F03.94, F03.A0, F03.A11, F03.A18, F03.A2, F03.A3, F03.A4, F03.B0, F03.B11, F03.B18, F03.B2, F03.B3, F03.B4, F03.C0, F03.C11, F03.C18, F03.C2, F03.C3, F03.C4 effective 10/1/2022.</p>										
<p>CR13249: NCD 220.6.20 removed from the NCD Manual as of 10/13/23 final reconsideration, ending CED and once-in-a-lifetime PET scans and permitting Medicare coverage determinations to be made by the MACs. (MCS 011K, 010K, FISS RC59233, CWF Error 5279)</p>										

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1) Coverage Determinations

Table of Contents

(Rev.12364; Issued:11-16-23)

Transmittals for Chapter 1, Part 4

220.6.20 – Beta Amyloid Positron Emission Tomography (*PET*) in Dementia and Neurodegenerative Disease (*RETIRED*)

220.6.20 - Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (*RETIRED*)

(Rev. 12364; Issued:11-16-23; Effective:10-13-23; Implementation:12-19-23)

Effective October 13, 2023, CMS removed NCD 220.6.20, ending CED for PET beta amyloid imaging and permitting Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act.